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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant:	THEEUWES et al.	Attorney Docket No.	Arc-2600R1
Serial No.:	08/988,292	Group Art Unit:	3763
Filed:	10 December 1997	Examiner:	RODRIGUEZ, C.
Title:	Device and Method for Enhancing Transdermal Agent Flux		

APPLICANTS' BRIEF ON APPEAL

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Filed herewith in triplicate is Applicant's Brief on Appeal. The Claims on appeal are attached hereto as an Appendix A.

Requirements of 37 C.F.R. § 1.192(c)

In compliance with the requirements of 37 C.F.R. § 1.192(c), Applicants provide the following:

(1) Real Party in Interest:

The real party in interest, an assignee of the subject patent application, is Alza 05/13/2002 CHOUMA 00000021 011173 08988292 Corporation, Mountain View, California. The real party in interest derives its interest by mesne assignment from the inventors.

(2) Related Appeals and Interferences

No other interferences known to Appellants, the Appellants' legal representatives or assignee will be directly affected by or have a bearing on the Board's decision on this case.

(3) Status of claims:

Claims 1-8 , 10-21 and 23-30 are pending in this application. Claims 23-27 and 30 have been deemed allowable. Claims 1-5, 8,10-12, 14,15, 18-21, 28, and 29 are rejected under 35 U.S.C. § 102(b) and § 103(a) in light of the cited prior art references. Claims 6, 7, 13, 16, and 17 have been objected to as being dependent from a rejected base claims but would allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The status of the claims is based upon latest Office Action dated 11 September 2001.

(4) Status of Amendments:

No amendment has been filed since the 11 September 2001 Office Action noted above.

(5) Summary of Invention:

The device of the present invention pierces the stratum corneum of a body surface to form pathways through which a substance can either be introduced (i.e. delivery) or withdrawn (i.e. sampling). In one aspect, the invention comprises a plurality of very small protrusions which extend through a connecting medium which facilitate making substantial contact with the body surface for either delivering or sampling of a substance. The delivery or sampling can be

accomplished at least in part by incorporating electrotransport technology, passive/diffusion technology, osmotic technology and pressure technology.

(6) Issues on Appeal:

a. Whether Appellants' claims 1-5, 10, 11, 14, 15, 18-20, 28, and 29 are properly rejected under § 102(b) as being anticipated by Lerner et al. (U.S. Patent No. 2,922,425).

b. Whether Appellants' claims 1, 8, 10, 11, 18-21 are properly rejected under § 102(b) as being anticipated by Kellett et al. (U.S. Patent No. 5,261,426).

c. Whether Appellants' claim 12 is properly rejected under 35 U.S.C.§ 103(a) as being obvious over Lerner et al. (U.S. Patent No. 2,922,425) in view of Gerstel et al. (U.S. Patent No. 3,964,482).

(7) Grouping of Claims

The claims on appeal: 1-5, 8,10-12, 14-15, 18-21, and 28-29 stand and fall together

(8) Argument

A. Rejection under § 102(b) over Lerner (U.S. Patent No. 2,922,425)

The Examiner has rejected claims 1-5, 10, 11, 14, 15, 18-20, 28 and 29 under 35 U.S.C. § 102(b) as being anticipated by Lerner at al. (U.S. Patent No. 2,922,425).

"Anticipation under 35 U.S.C. Section 102(b) requires the presence in a single prior art disclosure of each and every element of a claimed invention." Electro Med. Sys. S.A. v. Cooper Life Sciences , 34 F.3d 1048, 1052, 32 USPQ2d 1017, 1019 (Fed. Cir. 1994).

The key elements in the claims on appeal as pertains to this rejection are "body surface", "capable of piercing said body surface", and "said connecting medium is placed in contact with said body surface".

The disclosure of Lerner will be discussed generally and then specific teachings in Lerner will be cited to show that the above listed key elements are not disclosed in Lerner.

Lerner provides for a device which spreads hair treatment in the form of a lotion onto hair and specifically to apply hair-waving lotions to hair while it is wound upon a curler. As shown in Figs. 1 and 2, the device includes **Infusion Members 14** which are spaced along **Elongated Wall 12** which forms part of **Elongated Manifold Chamber 10**. **Channels 26** are formed within **Infusion Members 14** and penetrate into **Elongated Manifold Chamber 10**. Thus a pathway is provided for lotion to be conducted from **Elongated Manifold Chamber 10**, along the longitudinal axis of **Infusion Members 14**. The lotion exits the distal end of **Infusion Members 14** where it is applied directly to hair or to hair wound upon a curler. **Mass 32** is positioned on **Elongated Wall 12** so the **Infusion Members 14** penetrate through **Mass 32** which is made of resilient compressible bibulous material such a regenerated cellulose sponge, polyurethane sponge, felt, of the like.

1. Body Surface

The Examiner has asserted that it is unclear what body surface is being referred to. The Examiner has stated that a plastic film could be a body surface. Paragraph 6, page 4 of the 11 Sept. 2001 Office Action.

On page 21, lines 21-23, of the Applicants' specification, the following definition of body surface is provided:

> *The term "body surface" as used herein refers generally to the skin, mucous membranes, and nails of an animal or human, and to the outer surface of a plant.*

Based upon this definition, a plastic film cannot be a body surface. The Examiner further argues that the claims are not limited to the medical art. Paragraph 6, page 4 of the 11 Sept. 2001 Office Action.

In order to refute the Examiner's assertion, the Applicants would point out the definition for agent, given on page 5, lines 8-13 of the specification:

> *The terms "substance", "agent" and "drug" are used interchangeably herein and broadly include physiologically or pharmacologically active substances for producing a localized or systemic effect or effects in mammals including humans and primates, avians, valuable domestic household, sport or farm animals, or for administering to laboratory animals such as mice, rats, guinea pigs, and the like.*

The definitions of "body surface" and "agent" whether taken individually or in combination place the claims in the medical arts and establish an understanding for "body surface" as used in the present application and claims that distinguishes Applicants' claims from the cited prior art.

2. "Capable of Piercing..."

A second key element is the claim language "capable of piercing said body surface". The Examiner has asserted that this is "intended use" language. Further it is asserted that "If the prior art structure is capable of performing the intended use, then it meets the claim.

Applicant's response is two pronged. The first, even assuming *arguendo* that this language is "intended use" language, the prior art fails to perform the same intended use, as will be shown. Secondly, the Applicants asserts that this is not "intended use" language as will be discussed below.

2a. Capable of performing same function

Applicants' device is intended to pierce the outer layer of skin and deliver through the skin to the organism, therapeutic agents stored in the device. Alternatively, the device will sample or withdraw agent from the organism and store it in the device. In either embodiment, the body surface is pierced.

The focus of the Lerner invention is to apply lotion to the hair and to minimize the contact between the device and the scalp of the person. The following is given as an object of the Lerner invention:

> *One object of the present invention is to provide an applicator for applying a liquid treating material such as a permanent waving lotion to the hair with a minimum of loss and a minimum of contact between the lotion and the scalp.* Col 1, lines 36-40.

There is a clear intent to minimize the contact between the device and scalp (i.e. body surface) which logically means the device is not intended to and/or capable of piercing the scalp.

In addition, as shown in Figs. 10 and 11, the Lerner invention includes "two pairs of arcuate spacing members or arms, **56, 56**, one at each end of the applicator head, which serve to ensure that the infusion members **52** are spaced from the scalp....". These elements show a clear objective to reduce or eliminate contact between the Lerner invention and the body surface, which further shows that the Lerner invention was not designed to pierce the scalp.

2b. Intended Purpose

Applicants assert that the "intended use" language put forth by the examiner is not in fact a statement of intended use. Statements of intended use are often found in the preamble of the claims, reflect a work piece that the device is designed to operate upon, and/or a manner in which the device is used.

The language "the protrusions are capable of penetrating the body surface" is found in the body of the claim, not the preamble. The language does not simply disclose a body surface that the protrusions are applied to. It states that the protrusions have structural elements which enable them to pierce the body surface. This language does not describe intended use.

3. Contacting the Body Surface

As shown in the several quotes from the Lerner patent provide above, Lerner took special care to prevent the Infusion Members from touching the scalp. As shown in Fig. 8, when the Lerner device is applied to the hair, Mass 32 is compressed as the Infusion Members 14 are inserted into the hair. It is impossible for Mass 32 to contact a body surface, which in this case would likely to be the scalp.

Because all the elements of Applicants' claims have not been disclosed in the cited Lerner patent, Applicants request that the holding by the Examine of anticipation based upon the Lerner patent be reversed.

B. Rejection under § 102(b) over Kellett (U.S. Patent No. 5,261,426)

The Examiner has rejected claims 1, 8, 10, 11 and 18-21 under 35 U.S.C. § 102(b) as being clearly anticipated by Kellett (U.S. Patent No. 5,261,426).

As discussed above, the § 102 reference must contain all elements for the claims being rejected. In a manner similar to Lerner, the Kellett patent fails to disclose several key elements of the pending claims. These elements include "capable of piercing the body surface" and "contacting the body surface".

1. Body Surface

As discussed above, a definition of "body surface" has been provided in Applicants' specification which clearly shows that a plastic film is not a body surface and that hair tresses are also not a body surface as used in the present application. Further, the definitions of "body surface" and "agent" clearly establish that the claims are directed to the medical art.

2. "Capable of Piercing..."

As discussed above in relation to the Lerner patent, "capable of piercing" is not "intended use" language and even if it were, the prior art structure is not capable of performing the intended use.

Kellett discloses the foam pads attached to the tines of a convention styling brush. As is generally understood, a styling brush is not intended to pierce the scalp or any body surface. Therefore the Kellett device does not perform the same function.

3. "Contacting the body surface..."

The disclosure in Kellett is somewhat similar to that of Lerner. It provides for a foam matrix comprising water, hair conditioning agent, and a non-ionic surfactant. Preferably the foam matrix is attached to the tines of a styling brush or comb which is effective to condition and style hair.

As shown in Fig. 2, Foam Pad 1 is shown impaled on Tines 5 of Styling Brush 6. When used in a convention al manner, the hair is brought into contact with the pad, indicating that the device is not intended to bring the pad in contact with a body surface. Kellett, Col 15, lines 46-49.

Further, in Col 3, lines 38-40, it is disclosed that the pad "is intended to encompass any shaped foam body which is useful for manual application to the hair...". While discussing the foam nature of the pad, it is disclosed that the foam characteristics" ..permit the pad to effectively contact the individual hairs..". Col 4, lines 21-22. There is no indication in the disclosure that there was ever any intent to have the disclosed device contact a body surface or that there was any capability on the part of the disclosed invention to be able to contact a body surface.

When the pad is used with a conventional styling brush as described it would be impossible to force the pad into contact with a body surface with the pad impaled on the tines of the brush.

Because all the elements of Applicants' claims have not been disclosed in the cited Kellett patent, Applicants request that this holding by the Examiner of anticipation based upon the Kellett patent be reversed.

C. Rejection under § 103(a) based upon Lerner and Gerstel (U.S. Patent No. 3,964,482)

The Examiner has rejected claim 12 under 35 U.S.C. § 103(a) as being unpatentable over Lerner et al. (U.S. Patent No. 2,922,425) in view of Gerstel (U.S. Patent No. 3,964,482).

In support of that rejection the Examiner has asserted that Lerner discloses all elements of the Applicants' claims except for the protrusions comprising blades. As discussed above, there are a number of elements of the Applicants' claims that are not disclosed by Lerner in addition to the element in claim 12 that the protrusions are blades. Even the combination of Lerner and Gerstel does not disclose all of the elements of Applicant's claims.

In addition, the Examiner has but forth no proper evidence to support the combination of Lerner and Gerstel. Mere assertions that it would have been obvious to one skilled in the art at the time the invention was made does not support a *prima facie* case of obviousness. "Broad conclusory statements regarding the teaching of multiple references, standing alone, are not "evidence." In re Dembiczak, 98-1498 , Decided 28 April 1999 (CAFC).

As the Examiner has failed to make a prima facie case obviousness in regards to the § 103(a) rejection based upon Lerner in view of Gerstel, Applicants respectfully request that the rejection by the Examiner of claim 12 be reversed.

CONCLUSION

For the reasons set forth above, Appellants respectfully submit that the claims fully meet the provision of 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a). Accordingly Appellants respectfully request the reversal of each of the rejections on appeal.

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Respectfully submitted,

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Appendix: Claims On Appeal

1. A device for introducing or withdrawing an agent through a body surface, comprising:

a member having a body-surface-proximal side and a body-surface-distal side;

said member further having a first surface on the body-surface-proximal side of the member, a second surface on the body-surface-distal side of the member and a plurality of protrusions capable of piercing said body surface; said protrusions extending from the first surface; and

a connecting medium disposed on at least a portion of the first surface of the member, said connecting medium capable of storing the agent therein or passing the agent therethrough when the plurality of protrusions have pierced the body surface and said connecting medium is placed in contact with said body surface.

2. The device of Claim 1 wherein the member has an opening therethrough.

3. The device of Claim 2 wherein the connecting medium extends across the opening.

4. The device of Claim 2 wherein the connecting medium extends through the opening.

5. The device of Claim 2 wherein the connecting medium is in the opening.

6. The device of Claim 1 wherein the connecting medium is in the range of about 10 micrometers to about 100 micrometers thick.

7. The device of Claim 1 wherein the connecting medium is about 50 micrometers thick.

8. The device of Claim 1 wherein the connecting medium comprises a hydrogel.

9. Canceled.

10. The device of Claim 1 wherein the connecting medium comprises a form selected from the group consisting of a gel, a solid and a powder.

11. The device of Claim 1 wherein the connecting medium further comprises a matrix material.

12. The device of Claim 1 wherein the protrusions comprise blades.

13. The device of Claim 12 wherein at least one of the plurality of blades comprises means for anchoring the device to the body surface.

14. The device of Claim 2 further comprising an agent delivery device connected to the second surface of the member, the agent delivery device selected from the group consisting of an electrotransport device, a passive device, an osmotic device, and a pressure driven device.

15. The device of Claim 14 wherein the agent delivery device is capable of delivering at least one agent selected from the group consisting of an oligonucleotide drug, a polynucleotide drug, gene, a polypeptide, and a protein.

16. The device of Claim 1 further comprising a sampling device connected to the second surface of the member, the sampling device selected from the group consisting of a reverse electrotransport device, a passive device, and an osmotic device.

17. The device of Claim 16 wherein the sampling device is capable of sampling agents selected from the group consisting of body electrolytes, illicit drugs and glucose.

18. A device for introducing or withdrawing an agent through a body surface; comprising:

a member having a body-surface-proximal side and a body-surface-distal side; said member further having a first surface on the body-surface-proximal side of the member, a second surface on the body-surface-distal side of the member, and opening therethrough and a plurality of protrusions capable of piercing said body surface; said protrusions extending from the first surface; and

a connecting medium disposed on at least a portion of the first surface of the member and further disposed in the at least one opening, said connecting medium capable of storing the agent therein or passing the agent therethrough when the plurality of protrusions have pierced the body surface and said connecting medium is placed in contact with said body surface.

19. The device of Claim 18 wherein the connecting medium is disposed on a portion of the first surface.

20. The device of Claim 18 wherein the connecting medium is capable of storing an agent that is selected from the group consisting of an oligonucleotide drug, a polynucleotide drug, a gene, a polypeptide, and a protein.

21. The device of Claim 18 wherein the connecting medium comprises a hydrogel.

22. Canceled.

23. A method for introducing an agent through a body surface, comprising the steps of:

providing a member having a body surface proximal side, a body surface distal side, a first surface on the body surface proximal side of the member and a second surface distal side of the member; said member having a plurality of protrusions extending from the first surface and extending towards the body surface and a connecting medium disposed on at least a portion of the first surface;

introducing the agent in the connecting medium;

piercing the body surface with the plurality of protrusions extending from the first surface of the member;

contacting the body surface with the connecting medium; and

passing the agent through the body surface.

24. The method of Claim 23 wherein the passing step comprises:

administering the agent by a method selected from the group consisting of electrotransport, passive delivery, osmosis, and pressure.

25. The method of Claim 26 wherein the withdrawing step comprises:

withdrawing the agent by a method selected from the group consisting of reverse electrotransport, passive sampling, and osmosis.

26. A method for withdrawing an agent through a body surface, comprising the steps of:

piercing the body surface with a plurality of protrusions extending from a body surface proximal side of a member having a connecting medium capable of passing the agent

therethrough, the connecting medium disposed on at least a portion of the body surface proximal side;

contacting the body surface with the connecting medium; and

withdrawing the agent through the body surface.

27. A device for introducing or withdrawing an agent through a body surface, comprising:

a member having a body surface proximal side, a body surface distal side and a plurality of protrusions extending from said body surface proximal side;

a connecting medium capable of storing the agent therein or passing the agent therethrough on at least a portion of the body surface proximal side of the member; and

a sampling device connected to the body surface distal side, the sampling device selected from the group consisting of a reverse osmosis device, an electrotransport device, a passive device and an osmotic device.

28. The device of claim 1 further comprising an agent reservoir disposed on the second surface of the member.

29. The device of claim 28 where said agent reservoir is an element of an agent delivery apparatus selected from a group consisting of an electrotransport device, a passive device, an osmotic device and a pressure driven device.

30. A device for introducing or withdrawing an a gent through a body surface, comprising:

a member having a body surface proximal side, a body surface distal side and a plurality of protrusions extending from said body surface proximal side; said member further having at least one hole through the member,

a connecting medium capable of storing the agent therein or passing the agent therethrough on at least a portion of the body surface proximal side of the member; and

a sampling device connected to the body surface distal side, the sampling device selected from the group consisting of a reverse osmosis device, an electrotransport device, a passive device and an osmotic device.